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PFIZER INC., PHARMACIA CORPORATION,
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

MARY WOODALL,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-01183-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer") Pharmacia Corporation (f/k/a Monsanto Company¹) ("Pharmacia") and
3 G.D. Searle LLC ("Searle") and file this Answer to Plaintiff's Complaint ("Complaint"), and
4 would respectfully show the Court as follows:

5
6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
9 Celebrex® (celocoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally.
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time
11 periods in which Plaintiff was prescribed and used Celebrex®.

12 **II.**

13 **ORIGINAL ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
16 deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or
17 information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's
18 medical condition and whether Plaintiff used Celebrex®, and, therefore, deny the same.
19 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
20 FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that

21
22
23 ¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in
24 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the
25 laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia
26 Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
27 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
28 its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
agricultural business and does not and has not ever designed, produced, manufactured, sold,
resold or distributed Celebrex®. Given that Plaintiff alleges in the Complaint that Monsanto
Company was involved in distributing Celebrex®, see PLAINTIFF'S COMPLAINT at ¶ 7,
Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will
respond to the allegations directed at Monsanto Company.

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1 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
2 paragraph of the Complaint.

3 2. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 3. Defendants state that this paragraph of the Complaint contains legal contentions to which
7 no response is required. To the extent that a response is deemed required, Defendants admit that
8 Pfizer and Pharmacia do business in the State of Minnesota. Defendants deny the remaining
9 allegations in this paragraph of the Complaint.

10 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of
11 business in New York, and that it is registered to do business in the State of Minnesota.
12 Defendants admit that Pfizer may be served through its registered agent. Defendants admit that
13 Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and
14 Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time,
15 Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States, including
16 Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe
17 drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations
18 regarding "predecessors in interest" are vague and ambiguous. Defendants are without
19 knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny
20 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 5. Defendants admit that Searle is a Delaware limited liability company with its principal
22 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
23 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
24 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
25 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
26 Celebrex® in the United States to be prescribed by healthcare providers who are by law
27 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
28 the remaining allegations in this paragraph of the Complaint.

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1 6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
2 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
3 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
4 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
5 Celebrex® in the United States to be prescribed by healthcare providers who are by law
6 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
7 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
8 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
9 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
10 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
11 paragraph of the Complaint.

12 7. Defendants admit that in 1933 an entity known as Monsanto Company ("1933
13 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
14 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to
15 Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
16 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
17 its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
18 agricultural business and does not and has not ever manufactured, marketed, sold, or distributed
19 Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or
20 Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or
21 distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in
22 this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.
23 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is
24 incorporated by reference into Defendants' responses to each and every paragraph of the
25 Complaint referring to Monsanto and/or Defendants.

26 8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
27 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
28 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

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1 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
2 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
3 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
4 accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in
5 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries
6 of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
8 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
12 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
14 and effective when used in accordance with its FDA-approved prescribing information.
15 Defendants state that the potential effects of Celebrex® were and are adequately described in its
16 FDA-approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 10. Defendants state that the allegations in this paragraph of the Complaint regarding
20 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
21 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the
22 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 11. Defendants admit that Pfizer and Pharmacia do business in the State of Minnesota.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 12. Defendants admit that Pfizer and Pharmacia do business in the State of Minnesota.
26 Defendants are without knowledge sufficient to form a belief as to the allegations in this
27 paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the same.
28 However, Defendants admit that Plaintiff claims the amount in controversy satisfies the

1 jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph
2 of the Complaint.

3 **Response to Factual Allegations**

4 13. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations regarding Plaintiff's medical condition or whether Plaintiff used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or
11 damage and deny the remaining allegations in this paragraph of the Complaint.

12 14. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
14 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage
19 and deny the remaining allegations in this paragraph of the Complaint.

20 15. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
22 same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
23 consumers without substantial change from the time of sale. Defendants deny the remaining
24 allegations in this paragraph of the Complaint.

25 16. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
27 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 17. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin,
6 naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is
7 required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as
8 being a non-steroidal anti-inflammatory (“NSAID”) drugs. Defendants deny the remaining
9 allegations in this paragraph of the Complaint.

10 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
11 towards Defendants and, therefore, no response is required. To the extent that a response is
12 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
13 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
14 or knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.

15 19. Defendants state that the allegations in this paragraph of the Complaint are not directed
16 towards Defendants and, therefore, no response is required. To the extent that a response is
17 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
18 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
19 or knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.

20 20. Defendants state that the allegations in this paragraph of the Complaint are not directed
21 towards Defendants and, therefore, no response is required. To the extent that a response is
22 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
23 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
24 or knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.

25 21. Defendants state that the allegations in this paragraph of the Complaint are not directed
26 towards Defendants and, therefore, no response is required. To the extent a response is deemed
27 required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
28 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,

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1 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
2 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to
3 provide the proper context for the remaining allegations in this paragraph and Defendants
4 therefore lack sufficient information or knowledge to form a belief as to the truth of the
5 allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

6 22. Defendants state that the allegations in this paragraph of the Complaint regarding
7 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
8 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the
9 same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
10 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
11 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
12 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state
13 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
14 prescribing information. Defendants state that the potential effects of Celebrex® were and are
15 adequately described in its FDA-approved prescribing information, which was at all times
16 adequate and comported with applicable standards of care and law. Defendants deny any
17 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

18 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex®
19 on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of
20 Celebrex® for the following indications: (1) for relief of the signs and symptoms of
21 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
22 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
23 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (“FAP”)
24 as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the
25 remaining allegations in this paragraph of the Complaint.

26 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
27 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex®
28 in the United States to be prescribed by healthcare providers who are by law authorized to

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1 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
2 certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed,
3 tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
4 healthcare providers who are by law authorized to prescribe drugs in accordance with their
5 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
6 in accordance with its FDA-approved prescribing information. Defendants state that the
7 potential effects of Celebrex® were and are adequately described in its FDA-approved
8 prescribing information, which was at all times adequate and comported with applicable
9 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
10 allegations in this paragraph of the Complaint.

11 25. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 26. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
18 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
19 FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the
20 Complaint.

21 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny the allegations in this paragraph of the Complaint.

26 29. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on
5 June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
6 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
7 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
8 and respectfully refer the Court to the study for its actual language and text. Any attempt to
9 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
10 the Complaint.

11 31. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 32. Defendants state that the referenced study speaks for itself and respectfully refer the
15 Court to the study for its actual language and text. Any attempt to characterize the study is
16 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 33. Defendants state that the referenced Medical Officer Review speaks for itself and
19 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
20 attempt to characterize the Medical Officer Review is denied. Defendants state that the
21 referenced study speaks for itself and respectfully refer the Court to the study for its actual
22 language and text. Any attempt to characterize the study is denied. Defendants deny the
23 remaining allegations in this paragraph of the Complaint.

24 34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
25 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
26 language and text. Any attempt to characterize the transcripts is denied. Defendants state that
27 the referenced study speaks for itself and respectfully refer the Court to the study for its actual
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1 language and text. Any attempt to characterize the study is denied. Defendants deny the
2 remaining allegations in this paragraph of the Complaint.

3 35. Defendants state that the referenced articles speak for themselves and respectfully refer
4 the Court to the articles for their actual language and text. Any attempt to characterize the
5 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
6 refer the Court to the study for its actual language and text. Any attempt to characterize the
7 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 36. Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 37. Defendants state that the referenced articles speak for themselves and respectfully refer
12 the Court to the articles for their actual language and text. Any attempt to characterize the
13 articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 38. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
17 Court to the study for its actual language and text. Any attempt to characterize the study is
18 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 39. Defendants state that the referenced Medical Officer Review speaks for itself and
20 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
21 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 40. Plaintiff fails to provide the proper context for the allegations concerning "Public
24 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or
25 knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 41. Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 42. Defendants state that the referenced study speaks for itself and respectfully refer the
5 Court to the study for its actual language and text. Any attempt to characterize the study is
6 denied. Plaintiff fails to provide the proper context for the allegations concerning "Public
7 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or
8 knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 43. Defendants admit that there was a clinical trial called APC. Defendants state that the
11 referenced article speaks for itself and respectfully refer the Court to the article for its actual
12 language and text. Any attempt to characterize the article is denied. Defendants deny the
13 remaining allegations in this paragraph of the Complaint.

14 44. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Plaintiff fails to provide the proper context for the allegations concerning "Data Safety
17 Monitoring Board" in this paragraph of the Complaint. Defendants therefore lack sufficient
18 information or knowledge to form a belief as to the truth of such allegations, and, therefore, deny
19 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 45. Defendants state that the referenced article speaks for itself and respectfully refer the
21 Court to the article for its actual language and text. Any attempt to characterize the article is
22 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
24 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
25 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 47. Defendants state that the referenced Medical Officer Review speaks for itself and
28 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any

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1 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
2 allegations in this paragraph of the Complaint.

3 48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
4 the proper context for the allegations concerning “other Celebrex trials” contained in this
5 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
6 form a belief as to the truth of such allegations, and, therefore, deny the same. As for the
7 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that
8 the referenced study speaks for itself and respectfully refer the Court to the study for its actual
9 language and text. Any attempt to characterize the study is denied. Defendants deny the
10 remaining allegations in this paragraph of the Complaint.

11 49. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 50. Plaintiff fails to provide the proper context for the allegations regarding Merck and
15 Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or
16 knowledge to form a belief as to the truth of such allegations, and, therefore, deny the same.
17 Defendants state that the referenced studies speak for themselves and respectfully refer the Court
18 to the studies for their actual language and text. Any attempt to characterize the studies is
19 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 51. Defendants state that the referenced Medical Officer Review speaks for itself and
21 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
22 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
23 allegations in this paragraph of the Complaint.

24 52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
25 are not directed toward Defendants, and, therefore no response is required. To the extent that a
26 response is deemed required, Plaintiff fails to provide the proper context for the allegations
27 regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient
28 information or knowledge to form a belief as to the truth of such allegations, and, therefore, deny

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1 the same. Defendants state that the referenced study speaks for itself and respectfully refer the
2 Court to the study for its actual language and text. Any attempt to characterize the study is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
5 Complaint are not directed toward Defendants, and, therefore no response is required. To the
6 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
7 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
8 therefore lack sufficient information or knowledge to form a belief as to the truth of such
9 allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for
10 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
11 to characterize the study is denied. Defendants deny the remaining allegations in this paragraph
12 of the Complaint.

13 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
14 Complaint are not directed toward Defendants, and, therefore no response is required. To the
15 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
16 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
17 therefore lack sufficient information or knowledge to form a belief as to the truth of such
18 allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for
19 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
20 to characterize the study is denied. Defendants state that the referenced article speaks for itself
21 and respectfully refer the Court to the article for its actual language and text. Any attempt to
22 characterize the article is denied. Defendants deny the remaining allegations in this paragraph of
23 the Complaint.

24 55. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants deny the allegations in this
26 paragraph of the Complaint.

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1 56. Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 57. Defendants state that allegations in this paragraph of the Complaint are not directed
5 toward Defendants, and, therefore no response is required. To the extent that a response is
6 deemed required, Defendants state that the referenced article speaks for itself and respectfully
7 refer the Court to the article for its actual language and text. Any attempt to characterize the
8 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 58. Defendants deny the allegations in this paragraph of the Complaint.

10 59. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
15 remaining allegations contained in this paragraph of the Complaint.

16 60. Defendants deny any wrongful conduct and deny the allegations contained in this
17 paragraph of the Complaint.

18 61. Defendants deny any wrongful conduct and deny the allegations contained in this
19 paragraph of the Complaint.

20 62. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
25 paragraph of the Complaint.

26 63. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
28 same. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and
5 deny the remaining allegations in this paragraph of the Complaint.

6 64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
7 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
8 November 14, 2000. Defendants state that the referenced letters speak for themselves and
9 respectfully refer the Court to the letters for their actual language and text. Any attempt to
10 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of
11 the Complaint.

12 65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
13 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
14 letter for its actual language and text. Any attempt to characterize the letter is denied.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 66. Defendants state that the referenced article speaks for itself and respectfully refer the
17 Court to the article for its actual language and text. Any attempt to characterize the article is
18 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
20 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
21 letter for its actual language and text. Any attempt to characterize the letter is denied.
22 Defendants deny the remaining allegations in this paragraph of the Complaint.

23 68. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
28 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by

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1 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
4 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
12 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
13 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription
18 medication which is approved by the FDA for the following indications: (1) for relief of the signs
19 and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis
20 in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
21 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
22 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery);
23 (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and
24 symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants
25 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
26 Complaint.

27 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which at all times was adequate and comported with applicable standards of care and law.
3 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
4 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
5 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
6 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

7 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
12 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
13 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which at all times was adequate and comported with applicable standards of care and law.
23 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
24 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
25 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
28 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
2 paragraph of the Complaint.

3 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
14 the Complaint.

15 75. Defendants deny the allegations in this paragraph of the Complaint.

16 76. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.
28

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1 78. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
3 same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 79. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
10 remaining allegations in this paragraph of the Complaint.

11 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® are and were adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® are and were adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants state that the referenced study speaks for itself and respectfully refer the Court to the
22 study for its actual language and text. Any attempt to characterize the study is denied.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 83. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the

1 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® are and were adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 **Response to First Cause of Action: Negligence**

8 84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
9 Complaint as if fully set forth herein.

10 85. Defendants state that this paragraph of the Complaint contains legal contentions to which
11 no response is required. To the extent that a response is deemed required, Defendants admit that
12 they had duties as are imposed by law but denies having breached such duties. Defendants state
13 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
14 prescribing information. Defendants state that the potential effects of Celebrex® were and are
15 adequately described in its FDA-approved prescribing information, which was at all times
16 adequate and comported with applicable standards of care and law. Defendants deny any
17 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

18 86. Defendants state that this paragraph of the Complaint contains legal contentions to which
19 no response is required. To the extent that a response is deemed required, Defendants admit that
20 they had duties as are imposed by law but denies having breached such duties. Defendants state
21 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
22 prescribing information. Defendants state that the potential effects of Celebrex® were and are
23 adequately described in its FDA-approved prescribing information, which was at all times
24 adequate and comported with applicable standards of care and law. Defendants deny any
25 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26 87. Defendants state that this paragraph of the Complaint contains legal contentions to which
27 no response is required. To the extent that a response is deemed required, Defendants admit that
28 they had duties as are imposed by law but denies having breached such duties. Defendants are

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1 without knowledge or information sufficient to form a belief as to the truth of the allegations in
2 this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny
3 the same. Defendants state that Celebrex® was and is safe and effective when used in
4 accordance with its FDA-approved prescribing information. Defendants state that the potential
5 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
6 information, which was at all times adequate and comported with applicable standards of care
7 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint, including all subparts.

9 88. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 89. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 90. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 91. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition
5 or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any
6 wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the
7 remaining allegations in this paragraph of the Complaint.

8 92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 Answering the unnumbered paragraph following Paragraph 92 of the Complaint,
11 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
12 and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

13 93. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
14 Complaint as if fully set forth herein.

15 94. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time,
18 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States, including
19 Texas, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants admit that, during certain periods of
21 time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed,
22 co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare
23 providers who are by law authorized to prescribe drugs in accordance with their approval by the
24 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
25 consumers without substantial change from the time of sale. Defendants deny the remaining
26 allegations in this paragraph of the Complaint.

27 95. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of
Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining
8 allegations in this paragraph of the Complaint.

9 97. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining
14 allegations in this paragraph of the Complaint.

15 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
20 remaining allegations in this paragraph of the Complaint.

21 99. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
26 remaining allegations in this paragraph of the Complaint.

27 100. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
6 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
7 remaining allegations in this paragraph of the Complaint.

8 101. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 102. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
21 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
22 paragraph of the Complaint.

23 103. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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104. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

105. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

108. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

109. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
6 information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining
7 allegations in this paragraph of the Complaint, including all subparts.

8 111. Defendants admit to providing FDA-approved prescribing information for Celebrex®.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 112. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 113. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 114. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28

1 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
 2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
 4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
 6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
 8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 **Response to Fourth Cause of Action: Breach of Implied Warranty**

10 118. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
 11 Complaint as if fully set forth herein.

12 119. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
 13 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
 14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
 15 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
 16 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
 17 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
 18 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
 19 paragraph of the Complaint.

20 120. Defendants state that Celebrex® was and is safe and effective when used in accordance
 21 with its FDA-approved prescribing information. Defendants state that the potential effects of
 22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
 23 which was at all times adequate and comported with applicable standards of care and law.
 24 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
 25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
 27 with its FDA-approved prescribing information. Defendants state that the potential effects of
 28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 122. Defendants state that this paragraph of the Complaint contains legal contentions to which
4 no response is required. To the extent that a response is deemed required, Defendants state that
5 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
6 prescribing information. Defendants state that the potential effects of Celebrex® were and are
7 adequately described in its FDA-approved prescribing information, which was at all times
8 adequate and comported with applicable standards of care and law. Defendants deny any
9 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

10 123. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
13 medication which is approved by the FDA for the following indications: (1) for relief of the signs
14 and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis
15 in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
16 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
17 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery);
18 (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and
19 symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants
20 deny the remaining allegations in this paragraph of the Complaint.

21 124. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
28

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1 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
2 Complaint.

3 125. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
5 same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
6 consumers without substantial change from the time of sale. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 126. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
10 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

23 130. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
24 Complaint as if fully set forth herein.

25 131. Defendants state that this paragraph of the Complaint contains legal contentions to which
26 no response is required. To the extent that a response is deemed required, Defendants admit that
27 they had duties as are imposed by law but denies having breached such duties. Defendants state
28 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved

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1 prescribing information. Defendants state that the potential effects of Celebrex® were and are
2 adequately described in its FDA-approved prescribing information, which was at all times
3 adequate and comported with applicable standards of care and law. Defendants deny any
4 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 132. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint, including all subparts.

11 133. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint, including all subparts.

17 134. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
19 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint, including all subparts.

25 135. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 136. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
5 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 137. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
13 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 138. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
21 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 139. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the

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1 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 140. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
9 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
14 the Complaint.

15 141. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the
17 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

145. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

146. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

147. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

148. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

149. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8
9 **Response to Prayer For Relief**

10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
11 damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for
12 Relief," including all subparts.

13 **III.**

14 **GENERAL DENIAL**

15 Defendants deny the allegations and/or legal conclusions set forth in Plaintiff's
16 Complaint that have not been previously admitted, denied, or explained.

17 **IV.**

18 **AFFIRMATIVE DEFENSES**

19 Defendants reserve the right to rely upon any of the following or additional defenses to
20 claims asserted by Plaintiff to the extent that such defenses are supported by information
21 developed through discovery or evidence at trial. Defendants affirmatively show that:

22
23 **First Defense**

24 1. The Complaint fails to state a claim upon which relief can be granted.

25 **Second Defense**

26 2. Celebrex® is a prescription medical product. The federal government has preempted
27 the field of law applicable to the labeling and warning of prescription medical products.
28 Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable

1 federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon
2 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
3 and violate the Supremacy Clause of the United States Constitution.

4 **Third Defense**

5 3. At all relevant times, Defendants provided proper warnings, information and
6 instructions for the drug in accordance with generally recognized and prevailing standards in
7 existence at the time.

8 **Fourth Defense**

9 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
10 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
11 knowledge at the time the drug was manufactured, marketed and distributed.

12 **Fifth Defense**

13 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
14 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

15 **Sixth Defense**

16 6. Plaintiff's action is barred by the statute of repose.

17 **Seventh Defense**

18 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily
19 negligent, actively negligent or otherwise failed to mitigate his damages, and any recovery by
20 Plaintiff should be diminished accordingly.

21 **Eighth Defense**

22 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
23 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
24 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
25 liable in any way.

26 **Ninth Defense**

27 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
28 intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of

1 Defendants is therefore barred.

2 **Seventeenth Defense**

3 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
4 Defendants.

5 **Eighteenth Defense**

6 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
7 conditions unrelated to Celebrex®.

8 **Nineteenth Defense**

9 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
10 the doctrine of assumption of the risk bars or diminishes any recovery.

11 **Twentieth Defense**

12 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
13 preempted in accordance with the Supremacy Clause of the United States Constitution and by
14 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

15 **Twenty-first Defense**

16 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
17 the subject pharmaceutical product at issue was subject to and received pre-market approval by
18 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

19 **Twenty-second Defense**

20 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
21 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
22 and Plaintiff's causes of action are preempted.

23 **Twenty-third Defense**

24 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
25 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
26 issue under applicable federal laws, regulations, and rules.

27 **Twenty-fourth Defense**

28 24. Plaintiff's claims are barred in whole or in part because there is no private right of

1 action concerning matters regulated by the Food and Drug Administration under applicable
2 federal laws, regulations, and rules.

3 **Twenty-fifth Defense**

4 25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate
5 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
6 of Comment j to Section 402A of the Restatement (Second) of Torts.

7 **Twenty-sixth Defense**

8 26. Plaintiff's claims are barred or limited to a product liability failure to warn claim
9 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of
10 Restatement (Second) of Torts § 402A, Comment k.

11 **Twenty-seventh Defense**

12 27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical
13 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
14 to § 6 of the Restatement (Third) of Torts: Products Liability.

15 **Twenty-eighth Defense**

16 28. Plaintiff's claims are barred under § 4, *et seq.*, of the Restatement (Third) of Torts:
17 Products Liability.

18 **Twenty-ninth Defense**

19 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts
20 sufficient under the law to justify an award of punitive damages.

21 **Thirtieth Defense**

22 30. Defendants affirmatively aver that the imposition of punitive damages in this case
23 would violate Defendants' rights to procedural due process under both the Fourteenth
24 Amendment of the United States Constitution, Article I, § 17 of the Constitution of the State of
25 Minnesota, and the Constitution of the State of Texas, and would additionally violate
26 Defendants' rights to substantive due process under the Fourteenth Amendment of the United
27 States Constitution.
28

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Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Texas and Minnesota law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process

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protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Minnesota and Texas. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act

1 (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s
2 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
3 FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations,
4 and with the specific determinations by FDA specifying the language that should be used in the
5 labeling accompanying Celebrex®. Accordingly, Plaintiff’s claims are preempted by the
6 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
7 United States.

8 **Fifty-fourth Defense**

9 54. Plaintiff’s misrepresentation allegations are not stated with the degree of particularity
10 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

11 **Fifty-fifth Defense**

12 55. Plaintiff’s claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

13 **Fifty-sixth Defense**

14 56. Plaintiff’s causes of action are barred by Texas Civil Practice & Remedies Code §
15 82.007.

16 **Fifty-seventh Defense**

17 57. Plaintiff’s causes of action are barred by Texas Civil Practice & Remedies Code §
18 82.003.

19 **Fifty-eighth Defense**

20 58. Plaintiff’s causes of action are barred by Texas Civil Practice & Remedies Code §
21 16.012.

22 **Fifty-ninth Defense**

23 59. This action is subject to the proportionate responsibility provisions of Chapter 33 of the
24 Texas Civil Practice and Remedies Code, including (without limitation) the requirement of §
25 33.003 thereof that the trier of fact determine the relative responsibility of each claimant,
26 Defendants, and responsible third-party that may be joined in the suit.

27 **Sixtieth Defense**

28 60. If Plaintiff settles with any other person or entity, then Defendants reserves the right to

1 make a written election of credit for settlements.

2 **Sixty-first Defense**

3 61. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and
4 satisfaction.

5 **Sixty-second Defense**

6 62. Plaintiff's claims are barred in whole or in part because any alleged defect was not
7 known or not reasonably scientifically knowable at the time the product was distributed.

8 **Sixty-third Defense**

9 63. Plaintiff's claims are barred by their failure to comply with conditions precedent to the
10 right to recover.

11 **Sixty-fourth Defense**

12 64. Plaintiff's claims are barred in whole or in part by the doctrine of informed consent.
13 Plaintiff was informed of the risks associated with treatment and willingly consented to
14 treatment despite those risks. Specifically, Plaintiff gave informed consent to the prescribing
15 physicians before taking Celebrex®, alone or in combination with any other drug(s).

16 **Sixty-fifth Defense**

17 65. The duty to obtain Plaintiff's informed consent prior to prescribing Celebrex® alone or
18 in combination with any other drug(s) rested solely with the prescribing physicians.

19 **Sixty-sixth Defense**

20 66. Plaintiff may not assert a claim against Defendants for negligent misrepresentation as
21 Plaintiff did not suffer a pecuniary loss as a result of any alleged misrepresentation by
22 Defendants.

23 **Sixty-seventh Defense**

24 67. Plaintiff's claims of negligent misrepresentation are barred by the failure to justifiably
25 rely on any alleged misrepresentation of Defendants.

26 **Sixty-eighth Defense**

27 68. Plaintiff's claims of misrepresentation are barred because any alleged misrepresentation
28 on which Plaintiffs relied did not constitute a misrepresentation of material facts.

Sixty-ninth Defense

69. Plaintiff's claims for breach of warranty are barred in whole or in part by the Defendants' disclaimers.

Seventieth Defense

70. Plaintiff's claims for breach of warranty are barred in whole or in part because they are not in privity with Defendants.

Seventy-first Defense

71. Defendants assert the defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proved.

Seventy-second Defense

72. Plaintiff's claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance and/or usage of trade.

Seventy-third Defense

73. Plaintiff has failed to allege conduct warranting imposition of punitive damages under Texas law.

Seventy-fourth Defense

74. The standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do not include amounts intended as exemplary damages, which are impermissible in a compensatory damages award.

Seventy-fifth Defense

75. Plaintiff's claims for punitive or exemplary damages are subject to the limitations and requirements of Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008(b).

Seventy-sixth Defense

76. Because of the lack of clear standards, the imposition of punitive damages against Defendants is unconstitutionally vague and/or overbroad.

Seventy-seventh Defense

77. No act or omission of Defendants was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

Seventy-eighth Defense

78. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

JURY DEMAND

Defendants hereby demand a trial by jury.

VI.

PRAYER

WHEREFORE, Defendants pray that Plaintiff take nothing by this suit, that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

Dated: March 21, 2008.

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1 Dated: March 21, 2008

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2

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

MARY WOODALL,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-01183-CRB

) **RULE 7.1 STATEMENT**

) **JURY TRIAL DEMANDED**

Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.'s stock.
2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.
3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

March 21, 2008

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